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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,832	09/19/2005	Jay M. Edelberg	955-39 PCT-US	9990
23869 7590 10/05/2009 HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791				
EXAMINER				
AUDET, MAURY A				
ART UNIT		PAPER NUMBER		
1654				
MAIL DATE		DELIVERY MODE		
10/05/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/527,832

**Applicant(s)**

EDELBERG ET AL.

**Examiner**

MAURY AUDET

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 18, 33, 52, 66, 75, 86, 92, 102, 116, 127, 139, 147 and 157-165 is/are pending in the application.
- 4a) Of the above claim(s) 1, 18, 33, 52, 66, 75, 86, 102, 116, 139, 147 and 157 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 92, 127 and 158-165 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/15/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's response is acknowledged. Due to the new grounds of rejection, the action is sent Non-Final.

As noted previously, Applicant diligently points out the suggestions for potential support in the specification, that the Examiner provided Applicant in researching ways to address the 112 2nd paragraph rejection. Though one of Applicant's amendments (term "condition") has raised a new 112 2nd, as this is a result of Applicant's efforts in view of the Examiners suggestions, the Examiner is making the modified new grounds of rejection under 112 2<sup>nd</sup> Non-Final. Applicant is welcomed to telephone the Examiner should any questions as to amendment options hereafter arise.

### ***Election/Restrictions***

As stated previously, Applicant's election without traverse of Group I, claims 92, 127 and 158-165, as drawn to the elected peptide of the invention of SEQ ID NO: 4 - AARGQAV, in the reply filed on 5/9/08, is acknowledged.

### ***Claim Rejections - 35 USC § 112 2nd***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 92, 127 and 158-165 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 92 (and dependent claims 158-165) the amended phrase and thus claims are indefinite based on the amendment to a method of determining "healthy versus damaged areas" of a heart vasculature. The description only describes that SEQ ID NO: 4 is known to bind a single BDNF receptor: trkB and not any BDNF receptor; and only in the microvasculature, and not the broader vasculature. [IT IS SUGGESTED APPLICANT CONSIDER DISTINCTLY CLAIMING THE INVENTION TO BINDING trkB RECEPTOR AND MICROVASCULATURE]. trkB receptors were found to be more prevalent in older age individual's hearts, than younger age hearts. However, the description does not make the 'connection/nexus' that trkB receptors in the older art (v. fewer or none in the younger art) equate to ANY heart with trkB receptors as being "damaged". Namely, there is not a link between this specific receptor and what disorder/pathology it causes. Thus, it is unclear how the claimed invention can even determine a DAMAGED heart, let alone whether a heart is "healthy". The terms have not been quantified in such a way that any one using the invention would know that such a heart is damaged, or not damaged BUT MAY STILL BE, simply because binding of SEQ ID NO: 4 has been evidenced - thereby indicating that trkB receptors are present. As such, the metes and bounds of the invention, read in light of the description, only appear to indicate the latter - whether a/more than 1 trkB receptor is present or not. As to what if any DAMAGE the presence of this receptor can be correlated to, this is unclear and thus the claimed invention is indefinite as claimed, based on the lack of quantified definition of what equals a "healthy heart" and what equals a "damaged heart". A heart can still have "damage" however small, and be deemed otherwise "healthy" to one practitioner OR NOT to another. Or have a slight, completely unrelated factor to trkB and be deemed "damaged" - yet SEQ ID NO:

4 would have not binding thereof, if no trkB receptors were present - and thus, based on this method, the heart would be falsely determined as "healthy".

In separate independent claim 105, the term "damaged" is indefinite, for the same reasons of record discussed above.

CERTAIN PREVIOUS REJECTIONS UNDER 112 2<sup>nd</sup>, THAT WERE OVERCOME BY AMENDMENT ARE RECITED HERE FOR CONTINUITY OF RECORD TO EVIDENCE THE AMENDMENTS MADE DURING PROSECUTION THUS FAR

I. LAST REJECTION BEFORE AMENDMENT (condition now deleted):

The claims are now drawn, in e.g. amended claims 92, to the term "condition", in the preamble, as a replacement for the indefinite terms "old heart" or "old areas" of heart vasculature; whereby the elected peptide of SEQ ID NO: 4 is now directed to said "condition".

The term "condition" is ambiguous, and bears a dual meaning within the specification v. as claimed here; as both the "condition of the heart", e.g. relative strength or overall health is found in the specification; yet as claimed, it is phrased as "a condition", the latter of which would tend to connote e.g. a specific disorder or disease that may impact the heart (old or young). In either instance, Applicant must point out the specific definition to be applied, should this term be used hereafter, AND indicate how SEQ ID NO: 4 is able to determine "a condition"?

II. REJECTIONS BEFORE THAT BEFORE AMENDMENT TO ABOVE (old now deleted):

“Specifically, the term “old” in e.g. claims 92 and 127 is a relative term which renders the claim indefinite. The term “old” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The best the Examiner can find in terms of some litmus test for what falls within the realm of old (v. young) heart is found in para 73, where the description reveals that what is really meant by old is two things: a heart that is damaged or a heart that has undergone some sort of physiological changes distinct in form; either of which seems to produce either greater BDNF receptors or communication for SEQ ID NO: 4 to bind such, for some reason. Applicant needs to reassess the language used to claim the invention in order to distinctly claim a better relative degree of what the parameters of the invention are (e.g. not age per se, but damage and physiological changes resulting in receptor binding by SEQ ID NO: 4).

Deeper within this same rejection of relativity is claimed compound v. control. In other words SEQ ID NO: 4 (old or damaged receptor binding) v. SEQ ID NO: 1 (control, young heart receptor binding). Applicant may wish to consider distinctly claiming, e.g. the language of para 77, wherein ratio's are given upon which one can immediately envision the proportion of binding that must take place in order to distinguish a damaged/physiologically changed heart v. and unaltered heart and how that impacts binding of SEQ ID NO: 4 (v. e.g. SEQ ID NO: 1).”]

***Elected Invention Free of the Art***

SEQ ID NO: 4 was not found to be reasonably taught or suggested by the prior art of record.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA, 9/30/09

/Maury Audet/  
Examiner, Art Unit 1654  
Full Sign. Auth. Program